

Kaczmarek, Chris

From: Taub, Cynthia <CTaub@steptoe.com>
Sent: Friday, July 12, 2013 3:48 PM
To: Kaczmarek, Chris
Subject: FW: List of 158W Issues
Attachments: List of 158W Issues for Discussion with EPA - June 3 2013.pdf

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From: Taub, Cynthia
Sent: Friday, July 12, 2013 3:44 PM
To: 'ross.philip@epa.gov'; 'Kazmarek.chris@Epa.gov'
Cc: Goldberg, Seth; Allison_Starmann@americanchemistry.com
Subject: List of 158W Issues

Phil and Chris-

Attached is the list of issues that we had provided to Susan Lewis in advance of the June 12 meeting. This is not an exhaustive list of the Panel's concerns regarding the 158W rule, but it should be helpful in understanding the type of issues we believe need to be resolved.

We will wait to hear back from you on some potential meeting dates.

Best,

Cynthia

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AMERICAN CHEMISTRY COUNCIL BIOCIDES PANEL
And
CONSUMER SPECIALTY PRODUCTS ASSOCIATION

June 4, 2013

Susan Lewis
Director, Antimicrobials Division
Office of Pesticide Programs
Lewis.Susan@epamail.epa.gov

Dear Ms. Lewis:

Re: Request for a Meeting to Discuss Questions on Part 158W Final Rule

We appreciate your comments and background information on a range of topics, including particularly the new 158W regulation during recent meetings with the Panel and with CSPA. As discussed, Panel and CSPA member companies have raised a number of questions concerning implementation of the new regulation. In discussion with Jennifer McLain on May 31, a meeting with EPA to discuss these issues is scheduled for June 12, pending confirmation by EPA after review of the below listed issues.

In light of the early July effective date for the new regulation, the Panel and CSPA are anxious to understand EPA's thinking on these issues as promptly as possible.

The Panel and CSPA appreciate your willingness to discuss implementation issues and we look forward to a productive session.

Sincerely,

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AMERICAN CHEMISTRY COUNCIL BIOCIDES PANEL
And
CONSUMER SPECIALTY PRODUCTS ASSOCIATION

158W Topics for Discussion with EPA

June 4, 2013

1. Delineation of “Food Uses”

The 158W toxicology and residue chemistry data requirements indicate that some food uses are “direct” and some are “indirect” food uses. However, no definitions for either one appear in the new regulation definitions. The Panel and CSPA would like to understand EPA’s working definitions of these terms. In addition, the regulation makes clear that some nonfood uses also may be subject to certain residue chemistry data requirements when a dietary risk assessment may be needed. What are those uses, and what residue chemistry data requirements are relevant? How do requirements for residential-use products differ from those from products used outside the home? The requirements for those uses are not identified in the residue chemistry data requirement table, nor are the requirements clear for inert ingredients. This too would benefit from further explanation. Also, how does EPA plan to address inert ingredients for food uses? How will data requirements apply to them? Will inerts be treated differently for home use than for other use sites?

2. Calculation of Level of Residues in Food

The new 158W regulation differentiates testing requirements (toxicology and residue chemistry) for indirect food uses based on whether the level of residues is above 200 ppb or less than 200 ppb. EPA has stated, “The 200 ppb level is the concentration of antimicrobial *residues in or on the food item.*” (Emphasis added.) The Panel and CSPA would appreciate further explanation from AD as to what it means by this definition and how it will be applied. In addition, we would like to discuss whether the definition of residue in or on the food item will impact current regulations at 40 CFR 180.940 (and others), which are based on an at-use concentration.

3. Identification of Antimicrobial Use Sites

The Panel and CSPA understand that the Agency is developing an index to antimicrobial uses sites. We would like to discuss this index and possibilities for input prior to its finalization and approaches for future revisions. Does EPA envision this index as providing guidance on what are direct food, indirect food and nonfood uses?

4. Exposure Assessment Guidance

Within 158W, there are numerous triggers that depend upon calculation of exposure levels to determine which data requirements must be met. However, the Panel and CSPA cannot identify clear EPA guidance on how to calculate exposure levels. The preamble to 158W directs applicants and registrants to REDs or Registration Review documents for information on how

EPA assesses exposures. However, there is significant variability among those documents even for similar uses. We would like to discuss EPA's thinking in this area to better understand the regulation.

As background and a particularly important example of members' concerns, nontarget organism and environmental fate data requirements, numerous triggers for high tier testing are dependent upon calculation of an Estimated Environmental Concentration (EEC) (see, for example, all requirements related to testing with a Typical End Product and requirement for whole sediment chronic testing). However, the rule does not make clear how EPA intends to make those calculations. While the Panel and CSPA understand that the Agency intends to conduct assessments using components of E-Fast for some use patterns, how and when those assessments will be conducted and what assumptions will be made will have a significant impact of what data requirements registrants will need to have addressed in advance of submission. However, that guidance is not currently available. In contrast, for conventional chemicals, there is clear guidance on how environmental exposure calculations should be conducted (see at http://www.epa.gov/oppefed1/ecorisk_ders/ and the appropriate models at http://www.epa.gov/pesticides/science/models_db.htm).

5. EPA's Implementation Plan

The Panel and CSPA are interested in obtaining as much information as possible regarding the way in which EPA intends to address data requirements that are applicable to all registrants of the same active ingredient in a consistent manner. The timing and impact of any change regarding a potable water rinse on food contact surfaces has raised numerous concerns regarding additional requirements, and should be included in the discussion. Implementation concerns would also include the exposure assessment triggers discussed above, in which factors such as the EEC may need to be developed by EPA as prerequisites to data development decisions. A better understanding of all of these will facilitate members' planning, including new product development and budgeting. This discussion also should include data requirements for inerts.

6. Definition of Fungicide at 158.2203

Section 158.2203 defines fungicide as "a substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment." The Panel and CSPA are concerned with the limitation of this definition to pathogenic fungi. We would like to discuss EPA's thinking on this issue and explore whether a technical correction to remove that limitation might be possible.

By way of background, the Panel's and CSPA's comments submitted on PR 2012-X concerning mold make clear our concerns with limiting the term fungicide to products which make claims against pathogenic microorganisms and the impact such a change will have. In addition, the Panel and CSPA believe the new definition is not consistent with Section 158.2204, which defines public health claims for antimicrobials. Finally, in response to specific comments on the Proposed Rule, EPA modified the definitions of disinfectant to remove the phrase "of infectious or public health microorganism." A conforming change was not made in the definition of fungicide. We would like to understand EPA's reasoning in not making such a change.